

APPLICANT or PATENTEE: **Michael N. Pollak; Meir J. Stampfer; Edward Giovannucci**

Serial or Patent No.: **09/234,651**

Filed or Issued: **January 21, 1999**

For: **CIRCULATING INSULIN-LIKE GROWTH FACTOR-I AND PROSTATE
CANCER RISK**

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. § 1.9(f) and 1.27(d)) - NONPROFIT ORGANIZATION**

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF NONPROFIT ORGANIZATION: **Lady Davis Institute**

ADDRESS OF NONPROFIT ORGANIZATION: **Sir Mortimer B. Davis Jewish General Hospital
3755 Cote Ste-Catherine Road
Montreal, Quebec H3T 1E2, Canada**

NAME OF NONPROFIT ORGANIZATION: **The Brigham and Women's Hospital**
ADDRESS OF NONPROFIT ORGANIZATION: **75 Francis Street, Boston
Massachusetts 02115**

TYPE OF NONPROFIT ORGANIZATION: **TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE
(26 USC 501(a) AND 501(c)(3))**

I hereby declare that the above identified nonprofit organization qualifies as a nonprofit organization as defined in 37 C.F.R. § 1.9(e), for purposes of paying reduced fees to the United States Patent Office regarding the invention described in the application identified above.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled **CIRCULATING INSULIN-LIKE GROWTH FACTOR-I AND PROSTATE CANCER RISK** described in:

☐ the specification filed herewith.

☒ application serial no. **09/234,651**, filed **January 21, 1999**.

☐ patent no. _____, issued _____.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. § 1.9(d) or by any concern which would not qualify as a small business concern under 37 C.F.R. § 1.9(d) or a nonprofit organization under 37 C.F.R. § 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. § 1.27) ***SEE PAGE 2 HEREOF.**

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. § 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: **Gopal Savjani**
TITLE OF PERSON IF OTHER THAN OWNER: **President**
ADDRESS OF PERSON SIGNING: **445 Medical Center Boulevard
Webster, Texas 77598-4217**

*NAME OF PERSON SIGNING:

Brian N. Hicks

TITLE OF PERSON IF OTHER THAN OWNER:

**Director, Corporate Sponsored Research and Licensing
The Brigham and Women's Hospital, Inc.**

ADDRESS OF PERSON SIGNING

**75 Francis Street, Boston
Massachusetts 02115**

SIGNATURE: _____

DATE: _____

*NAME OF PERSON SIGNING:

Samuel O. Freedman

TITLE OF PERSON IF OTHER THAN OWNER:

**Director of Research, Lady Davis Institute
Sir Mortimer B. Davis Jewish General Hospital**

ADDRESS OF PERSON SIGNING

3755 Cote Ste-Catherine Road

Montreal, Quebec H3T 1E2, Canada

SIGNATURE: Samuel O. Freedman

DATE: June 26, 2000

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(d)) – NONPROFIT ORGANIZATION

Packet Number (Optional)

33267-14

Applicant, Patentee, or Identifier: Michael N. Polak, Meir J. Stampfer, Edward Giovannucci
Application or Patent No.: 60/072,580
Filed or issued: January 21, 1998
Title: Circulating Insulin-Like Growth Factor-I and Prostate Cancer Risk

I hereby state that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF NONPROFIT ORGANIZATION Lady Davis Institute
ADDRESS OF NONPROFIT ORGANIZATION 3755 Cote St., Catherine Road, Montreal
P.Q. Canada H3T 1E2
NAME OF NONPROFIT ORGANIZATION Brigham and Women's Hospital
ADDRESS OF NONPROFIT ORGANIZATION 75 Francis Street, Boston, MA 02115

TYPE OF NONPROFIT ORGANIZATION

- ☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
- ☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) AND 501(c)(3))
- ☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
(NAME OF STATE _____)
(CITATION OF STATUTE _____)

I hereby state that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in:

- ☐ the specification filed herewith with title as listed above.
- ☒ the application identified above.
- ☐ the patent identified above.

I hereby state that rights under contract or law have been conveyed to and remain with the nonprofit organization regarding the above identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities and that no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below:

- ☐ no such person, concern, or organization exists.
- ☒ each such person, concern, or organization is listed below.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Brian N. Hicks

TITLE OF PERSON IF OTHER THAN OWNER Director, Corporate Sponsored Research and Licensing, Brigham & Women's Hospital

ADDRESS OF PERSON SIGNING 75 Francis Street, Boston, MA 02115

SIGNATURE _____ DATE _____

NAME OF PERSON SIGNING Sam Freedman

TITLE OF PERSON IF OTHER THAN OWNER Director of Research, Lady Davis Institute

ADDRESS OF PERSON SIGNING Sir Mortimer B. Davis Jewish General Hospital 3755 Cote St., Catherine Road
Montreal, P.Q. Canada H3T 1E2

SIGNATURE Samuel O. Freedman DATE Dec 2, 1998

**STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(d)) - NONPROFIT ORGANIZATION**Patent Number (Optional)
33267-14

Applicant, Patentee, or Identifier: Michael N. Pollak, Meir J. Stampfer, Edward Giovannucci
Application or Patent No.: 80/072,580
Filed or Issued: January 21, 1998
Title: Circulating Insulin-Like Growth Factor-I and Prostate Cancer Risk

I hereby state that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF NONPROFIT ORGANIZATION Lady Davis Institute
ADDRESS OF NONPROFIT ORGANIZATION 3755 Cote St. Catherine Road, Montreal
P.Q. Canada H3T 1E2
NAME OF NONPROFIT ORGANIZATION Brigham and Women's Hospital
ADDRESS OF NONPROFIT ORGANIZATION 75 Francis Street, Boston, MA 02115

TYPE OF NONPROFIT ORGANIZATION

- ☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
- ☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) AND 501(c)(3))
- ☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
- (NAME OF STATE _____)
- (CITATION OF STATUTE _____)

I hereby state that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in:

- ☐ the specification filed herewith with title as listed above.
- ☒ the application identified above.
- ☐ the patent identified above.

I hereby state that rights under contract or law have been conveyed to and remain with the nonprofit organization regarding the above identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities and that no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below:

- ☐ no such person, concern, or organization exists.
- ☒ each such person, concern, or organization is listed below.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.29(b))

NAME OF PERSON SIGNING Brian N. HicksTITLE OF PERSON IF OTHER THAN OWNER Director, Corporate Sponsored Research and Licensing, Brigham & Women's HospitalADDRESS OF PERSON SIGNING 75 Francis Street, Boston, MA 02115SIGNATURE Brian N. Hicks DATE 12.15.98NAME OF PERSON SIGNING Sam FreedmanTITLE OF PERSON IF OTHER THAN OWNER Director of Research, Lady Davis InstituteADDRESS OF PERSON SIGNING Sir Mortimer B. Davis Jewish General Hospital, 3755 Cote St. Catherine Road, Montreal, P.Q. Canada H3T 1E2

SIGNATURE _____ DATE _____

APPLICANT or PATENTEE: **Michael N. Pollak; Meir J. Stampfer; Edward Giovannucci**

Serial or Patent No.: **09/234,651**

Filed or Issued: **January 21, 1999**

For: **CIRCULATING INSULIN-LIKE GROWTH FACTOR-I AND PROSTATE
CANCER RISK**

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. § 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN **Diagnostic Systems Laboratories, Inc.**

ADDRESS OF CONCERN **445 Medical Center Boulevard, Webster, Texas 77598-4217**

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. § 121.3-18, and reproduced in 37 C.F.R. § 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is in the average over the previous fiscal year of the concern of the persons employed on a full-time, parttime or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled **CIRCULATING INSULIN-LIKE GROWTH FACTOR-I AND PROSTATE CANCER RISK** described in:

- ☐ the specification filed herewith.
☒ application serial no. **09/234,651**, filed **January 21, 1999**.
☐ patent no. _____, issued _____.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. § 1.9(d) or by any concern which would not qualify as a small business concern under 37 C.F.R. § 1.9(d) or a nonprofit organization under 37 C.F.R. § 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. § 1.27) ***SEE PAGE 2 HEREOF.**

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. § 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING:

TITLE OF PERSON IF OTHER THAN OWNER:

ADDRESS OF PERSON SIGNING

Gopal Savjani

President

**445 Medical Center Boulevard
Webster, Texas 77598-4217**

SIGNATURE: _____

DATE: _____

*NAME OF PERSON SIGNING:

Brian N. Hicks

TITLE OF PERSON IF OTHER THAN OWNER:

**Director, Corporate Sponsored Research and Licensing
The Brigham and Women's Hospital, Inc.**

ADDRESS OF PERSON SIGNING

**75 Francis Street, Boston
Massachusetts 02115**

SIGNATURE: _____

Brian N. Hicks

DATE: _____

6/26/00

*NAME OF PERSON SIGNING:

Samuel O. Freedman

TITLE OF PERSON IF OTHER THAN OWNER:

**Director of Research, Lady Davis Institute
Sir Mortimer B. Davis Jewish General Hospital**

ADDRESS OF PERSON SIGNING

3755 Cote Ste-Catherine Road

Montreal, Quebec H3T 1E2, Canada

SIGNATURE: _____

DATE: _____

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(d)) - NONPROFIT ORGANIZATIONPacket Number (Optional)
33267-14

Applicant, Patentee, or Identifier: Michael N. Pollak, Meir J. Stampfer, Edward Giovannucci
Application or Patent No.: 60/072,560
Filed or Issued: January 21, 1998
Title: Circulating Insulin-Like Growth Factor-I and Prostate Cancer Risk

I hereby state that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF NONPROFIT ORGANIZATION Lady Davis Institute
ADDRESS OF NONPROFIT ORGANIZATION 3755 Cote St. Catherine Road, Montreal
P.Q. Canada H3T 1E2
NAME OF NONPROFIT ORGANIZATION Brigham and Women's Hospital
ADDRESS OF NONPROFIT ORGANIZATION 75 Francis Street, Boston, MA 02115

TYPE OF NONPROFIT ORGANIZATION

- ☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
- ☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) AND 501(c)(3))
- ☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
(NAME OF STATE _____)
(CITATION OF STATUTE _____)

I hereby state that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in:

- ☐ the specification filed herewith with title as listed above.
- ☒ the application identified above.
- ☐ the patent identified above.

I hereby state that rights under contract or law have been conveyed to and remain with the nonprofit organization regarding the above identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities and that no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below:

- ☐ no such person, concern, or organization exists.
- ☒ each such person, concern, or organization is listed below.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Brian N. HicksTITLE OF PERSON IF OTHER THAN OWNER Director, Corporate Sponsored Research and Licensing, Brigham & Women's HospitalADDRESS OF PERSON SIGNING 75 Francis Street, Boston, MA 02115

SIGNATURE _____ DATE _____

NAME OF PERSON SIGNING Sam FreedmanTITLE OF PERSON IF OTHER THAN OWNER Director of Research, Lady Davis InstituteADDRESS OF PERSON SIGNING Sir Mortimer B. Davis, Jewish General Hospital, 3755 Cote St. Catherine Road, Montreal, P.Q. Canada H3T 1E2SIGNATURE Samuel O. Freedman DATE Dec 2, 1998

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(d)) – NONPROFIT ORGANIZATION

Patent Number (Optional)
33267-14

Applicant, Patentee, or Identifier: Michael N. Pollak, Mel J. Stampfer, Edward Giovannucci
 Application or Patent No.: 60/072,560
 Filed or Issued: January 21, 1998
 Title: Circulating Insulin-Like Growth Factor-I and Prostate Cancer Risk

I hereby state that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF NONPROFIT ORGANIZATION Lady Davis Institute
 ADDRESS OF NONPROFIT ORGANIZATION 3755 Cote St. Catherine Road, Montreal
P.Q. Canada H3T 1E2
 NAME OF NONPROFIT ORGANIZATION Brigham and Women's Hospital
 ADDRESS OF NONPROFIT ORGANIZATION 75 Francis Street, Boston, MA 02115

TYPE OF NONPROFIT ORGANIZATION

- ☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
- ☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) AND 501(c)(3))
- ☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
 (NAME OF STATE _____)
 (CITATION OF STATUTE _____)

I hereby state that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in:

- ☐ the specification filed herewith with title as listed above.
- ☒ the application identified above.
- ☐ the patent identified above.

I hereby state that rights under contract or law have been conveyed to and remain with the nonprofit organization regarding the above identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities and that no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below:

- ☐ no such person, concern, or organization exists.
- ☒ each such person, concern, or organization is listed below.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.29(b))

NAME OF PERSON SIGNING Brian N. Hicks

TITLE OF PERSON IF OTHER THAN OWNER Director, Corporate Sponsored Research and Licensing, Brigham & Women's Hospital

ADDRESS OF PERSON SIGNING 75 Francis Street, Boston, MA 02115

SIGNATURE Brian N. Hicks DATE 12.15.98

NAME OF PERSON SIGNING Sam Freedman

TITLE OF PERSON IF OTHER THAN OWNER Director of Research, Lady Davis Institute

ADDRESS OF PERSON SIGNING Sir Mortimer B. Davis Jewish General Hospital, 3755 Cote St. Catherine Road, Montreal, P.Q. Canada H3T 1E2

SIGNATURE _____ DATE _____

APPLICANT or PATENTEE: **Michael N. Pollak; Meir J. Stampfer; Edward Giovannucci**

Serial or Patent No.: **09/234,651**

Filed or Issued: **January 21, 1999**

For: **CIRCULATING INSULIN-LIKE GROWTH FACTOR-I AND PROSTATE
CANCER RISK**

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. § 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN **Diagnostic Systems Laboratories, Inc.**

ADDRESS OF CONCERN **445 Medical Center Boulevard, Webster, Texas 77598-4217**

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. § 121.3-18, and reproduced in 37 C.F.R. § 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is in the average over the previous fiscal year of the concern of the persons employed on a full-time, parttime or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled **CIRCULATING INSULIN-LIKE GROWTH FACTOR-I AND PROSTATE CANCER RISK** described in:

- ☐ the specification filed herewith.
☒ application serial no. **09/234,651**, filed **January 21, 1999**.
☐ patent no. _____, issued _____.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. § 1.9(d) or by any concern which would not qualify as a small business concern under 37 C.F.R. § 1.9(d) or a nonprofit organization under 37 C.F.R. § 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. § 1.27) *SEE PAGE 2 HEREOF.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. § 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING:

TITLE OF PERSON IF OTHER THAN OWNER:

ADDRESS OF PERSON SIGNING

Gopal Savjani

President

445 Medical Center Boulevard

Webster, Texas 77598-4217

SIGNATURE: _____

DATE: June 12, 2000

*NAME OF PERSON SIGNING:

Brian N. Hicks

TITLE OF PERSON IF OTHER THAN OWNER:

**Director, Corporate Sponsored Research and Licensing
The Brigham and Women's Hospital, Inc.**

ADDRESS OF PERSON SIGNING

**75 Francis Street, Boston
Massachusetts 02115**

SIGNATURE: _____

DATE: _____

*NAME OF PERSON SIGNING:

Samuel O. Freedman

TITLE OF PERSON IF OTHER THAN OWNER:

**Director of Research, Lady Davis Institute
Sir Mortimer B. Davis Jewish General Hospital**

ADDRESS OF PERSON SIGNING

**3755 Cote Ste-Catherine Road
Montreal, Quebec H3T 1E2, Canada**

SIGNATURE: _____

DATE: _____

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(d)) – NONPROFIT ORGANIZATION

Packet Number (Optional)

33267-14

Applicant, Patentee, or Identifier: Michael N. Pollak, Meir J. Stampfer, Edward GiovannucciApplication or Patent No.: 60/072,580Filed or Issued: January 21, 1998Title: Circulating Insulin-Like Growth Factor-I and Prostate Cancer Risk

I hereby state that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF NONPROFIT ORGANIZATION Lady Davis InstituteADDRESS OF NONPROFIT ORGANIZATION 3755 Cote St., Catherine Road, Montreal,P.Q. Canada H3T 1E2NAME OF NONPROFIT ORGANIZATION Brigham and Women's HospitalADDRESS OF NONPROFIT ORGANIZATION 75 Francis Street, Boston, MA 02115**TYPE OF NONPROFIT ORGANIZATION**☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) AND 501(c)(3))☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA

(NAME OF STATE _____)

(CITATION OF STATUTE _____)

I hereby state that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in:

☐ the specification filed herewith with title as listed above.☒ the application identified above.☐ the patent identified above.

I hereby state that rights under contract or law have been conveyed to and remain with the nonprofit organization regarding the above identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities and that no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below:

☐ no such person, concern, or organization exists.☒ each such person, concern, or organization is listed below.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Brian N. HicksTITLE OF PERSON IF OTHER THAN OWNER Director, Corporate Sponsored Research and Licensing, Brigham & Women's HospitalADDRESS OF PERSON SIGNING 75 Francis Street, Boston, MA 02115

SIGNATURE _____

DATE _____

NAME OF PERSON SIGNING Sam FreedmanTITLE OF PERSON IF OTHER THAN OWNER Director of Research, Lady Davis InstituteADDRESS OF PERSON SIGNING Sir Mortimer B. Davis, Jewish General Hospital, 3755 Cote St., Catherine Road, Montreal, P.Q. Canada H3T 1E2SIGNATURE Samuel O. FreedmanDATE Dec 2, 1998

Patent Number (Optional)

33267-14

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(d)) – NONPROFIT ORGANIZATION

Applicant, Patentee, or Identifier: Michael N. Pollak, Mel J. Stampfer, Edward Giovannucci
Application or Patent No.: 80/072 580
Filed or Issued: January 21, 1998
Title: Circulating Insulin-Like Growth Factor-I and Prostate Cancer Risk

I hereby state that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF NONPROFIT ORGANIZATION Lady Davis Institute
ADDRESS OF NONPROFIT ORGANIZATION 3755 Cote St. Catherine Road, Montreal
P.Q. Canada H3T 1E2
NAME OF NONPROFIT ORGANIZATION Brigham and Women's Hospital
ADDRESS OF NONPROFIT ORGANIZATION 75 Francis Street, Boston, MA 02115

TYPE OF NONPROFIT ORGANIZATION

- ☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
- ☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) AND 501(c)(3))
- ☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
- ☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
(NAME OF STATE _____)
(CITATION OF STATUTE _____)

I hereby state that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in:

- ☐ the specification filed herewith with title as listed above.
- ☒ the application identified above.
- ☐ the patent identified above.

I hereby state that rights under contract or law have been conveyed to and remain with the nonprofit organization regarding the above identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities and that no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below:

- ☐ no such person, concern, or organization exists.
- ☒ each such person, concern, or organization is listed below.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Brian N. HicksTITLE OF PERSON IF OTHER THAN OWNER Director, Corporate Sponsored Research and Licensing, Brigham & Women's HospitalADDRESS OF PERSON SIGNING 75 Francis Street, Boston, MA 02115SIGNATURE Brian N. Hicks DATE 12.15.98NAME OF PERSON SIGNING Sam FreedmanTITLE OF PERSON IF OTHER THAN OWNER Director of Research, Lady Davis InstituteADDRESS OF PERSON SIGNING Sir Mortimer B. Davis Jewish General Hospital, 3755 Cote St. Catherine Road, Montreal, P.Q. Canada H3T 1E2

SIGNATURE _____ DATE _____

Date: 1/1/2001
HAYNES AND BOONE, L.L.P.
901 Main Street, Suite 3100
Dallas, Texas 75202-3789
Telephone: 214/651-5533
Facsimile: 214/651-5940
File: 28758.20
d.849861.1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MICHAEL N. POLLAK et al.

Serial No.: 09/234,651

Filed: January 21, 1999

For: CIRCULATING INSULIN-LIKE
GROWTH FACTOR-I AND
PROSTATE CANCER RISK

§
§
§
§
§
§
§
§
§
§
§

Group Art Unit: 1643

Examiner: Yvonne Eyler

HNB Attorney Docket No. 28758.20

POWER OF ATTORNEY

Assistant Commissioner For Patents
Washington, D. C. 20231

Sir:

The undersigned assignee of the above-identified application hereby appoints the following attorneys with full power of substitution and revocation, to prosecute the application, to make alterations and amendments therein, and to transact all business in the United States Patent Office connected therewith.

I appoint the following attorneys and/or agents:

Jeffrey M. Becker	Reg. No. 35,442	Warren B. Kice	Reg. No. 22,732
J.R. Bell	Reg. No. 26,528	Michael Balconi-Lamica	Reg. No. 34,291
Michael S. Bush	Reg. No. 31,745	Todd Mattingly	Reg. No. 40,298
Randall E. Colson	Reg. No. 40,566	David L. McCombs	Reg. No. 32,271
Michael A. Davis, Jr.	Reg. No. 35,488	David M. O'Dell	Reg. No. 42,044
Tim Headley	Reg. No. 31,765	Brandi W. Sarfatis	Reg. No. 37,713
Rita M. Irani	Reg. No. 31,028		

I request that all correspondence be directed to:

Tim Headley
HAYNES AND BOONE, L.L.P.
1000 Louisiana Street, Suite 4300
Houston, Texas 77002-5012

Telephone inquiries may be directed to Tim Headley at 713-547-2040.

All powers of attorney heretofore given are hereby revoked.

Respectfully submitted,

SIR MORTIMER B. DAVIS -
JEWISH GENERAL HOSPITAL

By:

Samuel O. Freedman

Samuel O. Freedman
Director of Research, Lady Davis Institute
3755 Cote Ste-Catherine Road
Montreal, Quebec H3T 1E2, Canada

Date: June 9, 2000

HAYNES AND BOONE, L.L.P.
901 Main Street, Suite 3100
Dallas, Texas 75202-3789
Telephone: 214/651-5000
Facsimile: 214/651-5940

File: 28758.20

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231	
on	<u>June 29, 2000</u>
	<u>Vikki Meriwether</u>
	Vikki Meriwether

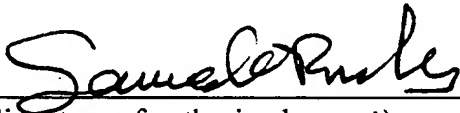
ADDED PAGE TO POWER OF ATTORNEY BY ASSIGNEE OF ENTIRE
INTEREST FOR AUTHORIZATION OF ATTORNEY(S) TO ACCEPT AND
FOLLOW INSTRUCTIONS FROM REPRESENTATIVE

The undersigned to this Power of Attorney hereby authorize(s) the U.S. attorney(s) named herein to accept and follow instructions pertaining to technical matters only from:

Michael N. Pollak;
Meir J. Stampfer; and
Edward Giovannucci; or

Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598-4217

as to any actions to be taken in the U.S. Patent and Trademark Office regarding this application without direct communication between the U.S. attorney(s) and the undersigned. In the event of a change in the person(s) from whom instruction may be taken, the U.S. attorney(s) will so be notified by the undersigned.


(Signature of authorized person)

Samuel O. Freedman
(Name of authorized person)

Director of Research, Lady Davis Institute
(Title of authorized person)